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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,116	01/26/2001	Howard Benjamin	PPI-012CN	9135

959 7590 03/08/2005

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HC

Office Action Summary	Application No.	Applicant(s)	
	09/772,116	BENJAMIN ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/3/04 has been entered.

2. The amendment filed on 12/3/04 has been fully considered and entered into the application.

3. Claims 1-7 and 10-23 are currently pending in this application.

Priority

This application is a continuation of application 08/573,786, filed on 12/18/95.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, 10-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The limitation 'a family of peptides that bind to the target' claimed in claims 1, 22-23 has no clear support in the specification and the claims as originally filed. The specification discloses

'once the peptide library is formed, a target of interest is screened with the peptide library to identify one or more library members that bind to target...' The subject matter claimed in claims 1, 22-23 broadens and/or alters the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

6. Claims 1-7, 10-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claims briefly recite a method for identifying a non-peptide compound that binds to a target, the method comprising: a) forming a first library of peptides; b) selecting from the first library a family of peptides that bind to the target; c) determining the amino acid sequence of the family of peptides and generating a peptide motif; d) forming a second library comprising non-peptide compounds; e) selecting from the second library at lest one-non-peptide compounds that bind to the target; f) determining the structure of at least one non-peptide compound; g) thereby identifying the non-peptide compounds that binds the target.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Although directed to DNA compounds, this holding would be deemed to be applicable to any compound; which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

The instant specification disclosed general, well-known peptide synthesis methods. The specification further discloses narrative, hypothetical methods of generating peptide libraries and identifying the active compound from the library and use the compound to generate peptide analogue libraries (second libraries), and screening the peptide analogue library for a ligand which binds the target. The specification discloses that the first peptide library is screened with a target, and once the sequences of peptides that bind to the target is selected, a 'peptide motif' is generated. The specification discloses that the peptide motif for the target of interest, a second

non-peptide library based on the peptide motif is generated. The specification discloses second library comprising analog library or the second library is synthesized based on altering D and L-amino acids; or the second library synthesized based on introduction of peptide mimetics at one or two positions within the library.

The specification has not disclosed the structure of the non-peptides of the second library or the non-peptides compounds, which bind to target and has binding affinity of at least 10^{-7} M, 10^{-8} M or 10^{-9} M.

The working example of the specification are drawn to construction of phage library (first library) comprising sixteen amino acids length and have amino acid sequence of SEQ ID NO: 1; screening the first library with LHRH-R, and from the selected peptides, SEQ ID NO: 6 is determined as the peptide motif of interest; based on the peptide motif a second library which is analog library or a mimetic library; screening the second library to identify members which bind to LHRH-R. The specification has not disclosed the non-peptides generated using the peptide motif of SEQ ID NO: 6, and has not disclosed the binding affinity of the non-peptides generated based on the peptide motif of SEQ ID NO: 6 to the LHRH-R (target).

The specification has not disclosed how the peptide motif is derivatized or substituted to obtain the peptide mimetics, or the analogues. The specification has not disclosed the structure of the non-peptides. The specification has not disclosed the use of the non-peptide compounds identified from the second library. The working example in the specification does not disclose the non-peptides, and whether the identified non-peptide is used in any other methods. The specification discloses that the identified non-peptide from the second library can be used to generate a third library.

The specification disclosure is hypothetical, and does not disclose the length of the peptide library or the position of modifications or substitutions of the peptide motif to generate the second library, or the number of modifications in the peptide motif or the target used. The specification disclosed hypothetical method, which requires to identify the peptides in a library that bind to the target, and then further methods of generating a peptide motif, which is specific to the target, and then further use of the peptide motif in generating second non-peptide library. The working example in the specification is drawn to a single species of specific peptide motif and method of generating a second non-peptide library. However, the working examples do not disclose the non-peptide identified by the claimed method, and/or the structure of the non-peptide compound identified.

And further the claimed method depends upon finding a peptide or family of peptides that selectively bind to a target, and generating a peptide motif specific to the target and further use of thus generated peptide motif to generate a non-peptide (or analogue) library and further screening the non-peptide library for members which bind to the target. Thus, applicants are not in possession of the peptide members, which bind to the target, and peptide motif and the non-peptides, and it would be impossible to practice the claimed method, since applicants are not in possession of the compounds, which are essential to practice the claimed method.

Further the specification disclosure of second library comprising non-peptide compounds clearly do not provide an adequate representation regarding the open ended claimed non-peptide library compounds made and screened by the presently claimed invention. The instant claim non-peptide compounds would read on peptide derivatives, peptidomimetics or peptide analogues, or small organic molecule compounds which specification has no written support.

In the present instance, the claimed method contains no identifying characteristics regarding the peptide members identified (from the first library) or the peptide motif, or the non-peptide compounds of the second library.

Additionally, the narrow scope of example is directed to one single peptide of 16 amino acids in length, which binds to LHRH-R, and method of generating peptide analogs or peptidomimetic compounds, clearly not representative of the scope of the presently claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-7, 10-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, 10-23 are vague and indefinite by reciting 'non-peptide', which are selected from peptide derivatives or analogues or peptidomimetics, wherein a single amino acid or few specific amino acids are replaced by synthetic or non-natural amino acids. However, the specification has not disclosed how many amino acids replaced and which amino acids were replaced, and further the term 'non-peptide' may read on small organic molecules which were not the peptide derivatives or peptide analogues or contain the non-natural amino acids as in applicants disclosure. Thus, the metes and bounds of the term non-peptide' is not clear.

The instant claims recite 'family of peptides', which is vague and indefinite. The term 'family of peptides' would refer to a group of peptides, which share similar properties, such as

epitopes or binding affinity or mimic a specific property. However, it is not clear which peptides are considered as family of peptides.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-7, 10-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility.

According to the text of 35 USC sec. 101, an invention must be "useful". Our reviewing courts have applied the labels, "specific utility" (or "practical utility") to refer to this aspect of the "useful invention" requirement of sec. 101. (Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980)). In Nelson, the court characterized "specific utility" (or "practical utility") as "a shorthand way of attributing real-world value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner, which provides some immediate benefit to the public." (Id. at 856.)

The non-peptide compounds identified by the instant claimed method are not supported by a specific, substantial, asserted utility and do not, without further research and experimentation, provide an immediate benefit to the public. The non-peptide compounds identified may bind to LHRH-R, however the specification has not taught the substantial utility of these compounds. The specification discloses that the non-peptides which bind to LHRH-R are identified, however has not disclosed the binding affinity or dissociation constant of the non-peptides with the LHRH-R, or assay in which the binding of the non-peptides with the LHRH-R

were tested. Rather, the identified non-peptide compounds require further research to identify whether the compounds are useful in therapy or diagnosis. The specification discloses that 'to optimize the benefits of both peptide based and chemically based libraries, the methods of the invention involve utilizing information obtained from screening a target with a first library comprising a multiplicity of peptides in the design of a second library comprising multiplicity of non-peptide compounds.' The specification discloses that the methods provide diversity and ease of deconvolution of traditional peptide library. The specification has not disclosed the high affinity compounds identified or the use of these high affinity compounds. Thus, any benefit to the public (to one of ordinary skill in the art) is speculative of the claimed method. There is no basis in the specification upon which to conclude that *any* of the non-peptides encompassed by the second library are, or will turn out to be, biologically active (therapeutic or diagnostic) after testing. Thus, the biomedical research contemplated by applicants is to take place at some future time, only when the properties of the claimed compounds have been elucidated by the experimental methods (screening assays) to which the specification alludes. Absent a disclosure of those properties, the asserted utility lacks specificity. Note, because the claimed invention is not supported by a specific asserted utility for the reasons just set forth, credibility cannot be assessed.

This is not to say that inventions that are to be used exclusively in a research setting (i.e., research tools) always lack a specific asserted utility. Indeed, many research tools such as telescopes, gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility. (See USPTO Utility Guidelines, page 12.) However, inventions that have a specifically identified utility must be distinguished from those whose

utility requires further research to identify or reasonably confirm. (Id.) Research tools (such as gas chromatographs, screening assays, etc.) are useful in the sense that they can be used in conjunction with other method steps to evaluate materials other than themselves or to arrive at some result. The non-peptide compounds identified by the claimed methods are not research tools in this sense. Rather, they are themselves the subject of basic research, whose usefulness or lack thereof has yet to be established. Merely labeling the instant libraries as "research tools" does not impart the specific utility required by this statute.

In the absence of an asserted specific utility, the "useful" requirement may be established by reference to a well-established utility. A "well established utility" is a "specific utility" which is well known, immediately apparent and implied by the specification based on the disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The non-peptide compounds identified by the claimed method, which lack a common core structure are not supported by a well established utility, however, because neither the specification as filed nor any art of record discloses or suggests any property or activity for the compounds such that another non-asserted utility would be well established for the compounds. Note, just because the specification discloses that the non-peptides bind to LHRH-R does not mean that the compounds have substantial utility. The specification has not disclosed the structural and functional properties of the non-peptides. The specification has not disclosed the non-peptides or the structures of the non-peptides identified by binding to LHRH-R. And further the specification has not disclosed the function of the non-peptides, which bind to LHRH-R, and binding to LHRH-R is not considered as substantial utility. Further, the non-peptides of the claimed libraries are not recognizable as analogous to compounds with a recognized pharmacological (or

other) activity, without the structures of the non-peptides. In the absence of any data as to their structure and activity, there is no basis upon which to base either a specific or a well-established utility.

Claims 1-7, 10-23 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-3, 5-7, 10-16, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al (US Patent 5,650489) and Gallop et al (Journal of Medicinal Chemistry. Vol. 37, Number 9, April 1994, pages 1233-1251).

The instant claims briefly recite a method for identifying a non-peptide compound that binds to a target, the method comprising: a) forming a first library of peptides; b) selecting from the first library a family of peptides that bind to the target; c) determining the amino acid sequence of the family of peptides and generating a peptide motif; d) forming a second library comprising non-peptide compounds; e) selecting from the second library at lest one-non-peptide compounds that bind to the target; f) determining the structure of at least one non-peptide compound; g) thereby identifying the non-peptide compounds that binds the target.

Lam et al teach library of bio-oligomers of defined size and known composition, in which the library contains all of the possible sequences of the bio-oligomers, and methods of synthesis of the library, and the bio-oligomers are peptides. And the reference methods include methods to identify bio-oligomer from the library that demonstrate the desired characteristics, such as binding (refers to the instant claim steps a-b) (i.e., see the abstract). The reference teaches that the method may be used for synthesis of random peptides as well as for synthesis of a peptide library that comprise pre-determined sequences (i.e., see column 10). The reference teaches that the method includes steps of generating a random library of peptides; contacting the library with target (acceptor); and isolating the library members which exhibit binding to the target; and sequencing the identified library members (i.e., see column 5).

Lam et al teach that the peptide libraries comprising D-amino acids, peptidomimetics, peptidomimetic bonds, and non-classical amino acids (i.e., see column 11-13). The reference

teaches that the structure of the peptides comprising non-classical peptides is determined by mass spectral analysis (i.e., see column 13). The reference teaches the methods for modification or derivatization of the peptides in the library (i.e., see column 13, 14). Lam et al teach that the peptides comprising D-amino acids (non-peptides of the instant claims) will be resistant to L-amino acid-specific proteases in vivo. And the reference teaches that the modified peptide bond compounds (non-peptides) would be resistant to peptide bond hydrolysis, and such libraries would provide ligands with unique function and activity, such as extended half-lives in vivo due to resistance to metabolic breakdown or protease activity (i.e., see column 11)

The reference teaches that the bio-oligomers of interest discovered during an initial screening need not be final ligands. In fact, it is preferable to synthesize a second library based on common sequences (peptide motif) of the ligands selected during the first screening,. In this way, one may be able to identify ligands of higher activity. (i.e., see column 16, last paragraph bridging column 17).

The claimed invention differs by reciting 'forming a second library comprising non-peptide compounds, and selecting at least one non-peptide that binds to the target. Lam et al teach peptide or peptide analog library synthesis and methods of screening the library for a ligand that binds to a target. Lam et al teach that a second library can be generated using the ligand identified during the initial screening, and advantages of the methods. Lam et al do not teach that the second library which is based on the ligand identified from the initial (first) library is non-peptide. However, Lam et al teach the use of D-amino acids or non-natural amino acids in the synthesis of the peptide libraries. A person skilled in the art would have been motivated to use the methods of synthesis of peptides and non-peptides taught by Lam et al to synthesize a

second library based on the ligand selected from the first library, and identify the non-peptide compound which binds to the target, and determine the structure of the compound, because Lam et al teach that the method would allow to identify higher affinity or active compounds. And it would have been obvious to one skilled in the art at the time the invention was made to make multiple (or a third) library based on the non-peptide selected and screen the library for active compounds, such more diverse or higher affinity compounds would be identified.

Gaollop et al review the applications of combinatorial technologies to Drug Discovery and peptide combinatorial libraries. Gallop et al teach the building block strategy , and the number of possible different individual compounds, N, prepared depends on number of building blocks used in each step, b, and number of synthetic steps in the reaction scheme, x, Gallop et al teach the phage display peptide libraries and methods of screening for active peptides. Gallop et al teach phage display libraries of 10^7 to 10^8 recombinants. The reference teaches antibody library synthesis, and method of screening with an antigen, and in vitro affinity improvements of the large number of selected clones. The in-vitro affinity improvement is accomplished by continuing selection of the pool of antibodies, or by introducing sequence variation into the enriched antibody pool and reapplying selection (see right column in page 1236). Further the article includes combinatorial libraries using multipin synthesis, and mimotope strategy. Peptide mixtures (libraries) were synthesized using the 20 common L-amino acids, and screened for antibody binding, and the identified sequence then provides a basis for a further round of synthesis, in which both L- and D- amino acids, non- or other amino acids are used. Thus, it was well known at the time the invention was filed to use the ligands identified in the first library as

basis to synthesize a second library with non-natural amino acids and screen for improved activity ligands.

Thus a person skilled in the art would have been motivated to use the ligands (peptides) identified in the first library as basis for synthesis of non-peptide libraries because the non-peptide compounds would be useful as pharmaceuticals or in therapy since the non-peptide compounds are resistant to proteolysis and have better half-lives in vivo.

14. Claims 1-7, 10-16, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al (US Patent 5,650,489) and Gallop et al (Journal of Molecular Medicine, vol. 37, no. 9, pages 1233-1251) as applied to claims 1-3, 5-7, 10-16, 21-23 above, and further in view of Benjamin et al (US Patent 6,475,806 B1).

Lam and Gallop et al have been discussed supra. The claimed invention differs from the combined teachings of Lam et al and Gallop et al, by reciting the first library is anchor library. Lam et al teach peptide or peptide analog library synthesis and methods of screening the library for a ligand that binds to a target. Gaollop et al review the applications of combinatorial technologies to Drug Discovery and peptide combinatorial libraries. Neither Lam et al , nor Gallop et al teach 'anchor library.' However, Benjamin et al teach anchor libraries and identification of peptide sequences of peptide binding sequences. The anchor library taught by Benjamin et al has same sequence as the instant specification peptide sequences. Benjamin et al teach that the anchor library is used to identify a peptide sequence that binds to the target. Thus, it would have been obvious to use the anchor libraries taught by Benjamin et al with the instant claimed method.

15. Claims 1-7, 10-17, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al (US Patent 5,650,489) and Gallop et al (Journal of Molecular Medicine, vol. 37, no. 9, pages 1233-1251) as applied to claims 1-7, 10-16, 21-23 above, and further in view of Stankova et al (Drug Development Research, vol. 33, pages 146-156, 1994).

Lam and Gallop et al have been discussed supra. The claimed invention differs from the combined teachings of Lam et al and Gallop et al, by reciting the use of tandem mass spectrometry to analyze the structure of the non-peptide compound. However, Stankova et al teach the use of tandem mass spectrometry for analysis of structure of compounds identified fro a library. Thus, it would have been obvious to one skilled in the art at the time the invention was made to use tandem mass spectrometry to analyze the non-peptide compounds identified.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-7, 10-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/610,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the reference and instant claimed methods are drawn to identifying non-peptide compounds, and the reference methods only differ by reciting 'biologically generated' first library which would include phage display library of instant claim 2; and further the reference method recites 'at least one peptide that binds to target' which is open to the instant claim method 'a family of peptides that bind to the target.'

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

18. Applicant's arguments with respect to the rejections of claims 1-7, 10-23, have been considered but are moot in view of the new ground(s) of rejection.

19. Applicant's arguments regarding 'family of peptides' filed on 12/3/04, have been fully considered but they are not persuasive.

Applicant's response addressing the 'family of peptides' has been considered. Applicants argue that the specification discussed a method to identify one or more compounds that bind to

leutinizing hormone releasing hormone receptor, a member of G-protein coupled, seven transmembrane receptor family of peptides.

From applicant's arguments, it is clear that the leutinizing hormone releasing hormone receptor(LHRH-R) is a member of the family of seven transmembrane receptors. However, it is not clear 'the family of peptides' of the instant claims include peptides that bind to the family of seven transmembrane receptor family or peptides which bind to only the LHRH-R.

Applicants further argue it is well known in the art as indicated by the references provided (Appendices A-C). However, in each of those references discuss specific family of peptides, which share a common core structure, or structural homology which is not clear in this application.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

03 March 2005

PADMASHRI PONNALURI
PRIMARY EXAMINER